

## **REMARKS/ARGUMENTS**

Favorable reconsideration of this application is requested in view of the following remarks:

### **Advisory Action**

Applicant acknowledges non-entry of the proposed amendments submitted on October 28, 2005.

### **Disposition of Claims**

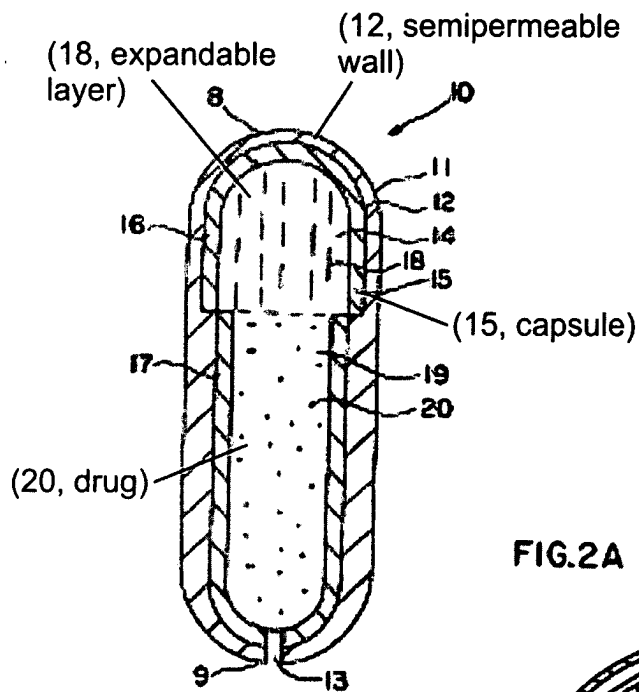
Claims 12-15, 17, 18, and 24 are pending in this application.

### **Rejections under 35 U.S.C. §103**

A. Claims 12-15, 17, 18, and 24 were rejected under 35 U.S.C. §103(a) as being obvious over Wong et al. (U.S. Patent No. 5,324,280). This rejection is respectfully traversed.

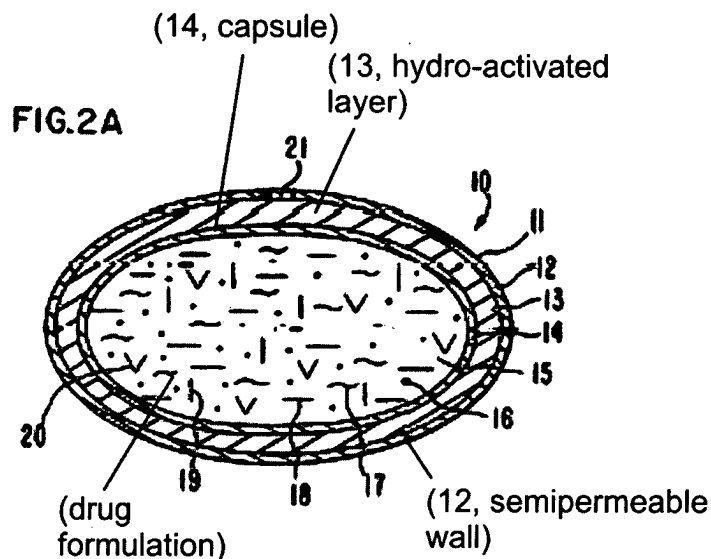
Claim 12 recites a sustained-release dosage form for the delivery of a progestogenic steroid. The dosage form comprises a capsule and a self-emulsifying drug formulation contained within a first portion of the capsule, wherein the self-emulsifying drug formulation contains a progestogenic steroid. The dosage form further comprises an expandable layer contained within a second portion of the capsule, wherein the expandable layer is positioned such that the self-emulsifying drug formulation can be expelled from the capsule upon expansion of the expandable layer. The dosage form further comprises a semipermeable membrane formed over at least a portion of an outer surface of the capsule.

Wong et al. teach an osmotic dosage form wherein a drug formulation is contained within a capsule. The capsule itself is encapsulated within a hydro-activated layer (or expandable layer). This is in contrast to the invention recited in claim 12 wherein the expandable layer is contained within the capsule. The figure below is a side-by-side comparison of a representation of the dosage form recited in claim 12 and the osmotic dosage form disclosed in Wong et al.



**FIG. 2**

Instant Application



Wong et al.

It is clear from the above and the disclosure of Wong et al. that Wong et al. do not teach locating an expandable layer and a self-emulsifying progestogenic steroid formulation within the same capsule. The Examiner has not cited any other references to overcome this deficiency in Wong et al. The Examiner has also not demonstrated that it is obvious to locate an expandable layer and a self-emulsifying progestogenic steroid formulation within the same capsule.

From the foregoing, claim 12 is not obvious over Wong et al. Withdrawal of the rejection of claim 12 over Wong et al. is respectfully requested. Claims 13-15, 17, 18, and 24, being dependent from claim 12, are likewise patentable over Wong et al. in view of the foregoing arguments. Withdrawal of the rejection of these claims is respectfully requested.

B. Claims 12-15, 17, 18, and 24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (U.S. Patent No. 6,458,373) in view of Wong et al. This rejection is respectfully traversed.

Lambert et al. teach an  $\alpha$ -tocopherol emulsion in the form of a self-emulsifying system encapsulated in a soft or hard gelatin capsule. Lambert et al. do not teach or disclose that an expandable layer is contained within the capsule that contains the emulsion. Wong et al., which has been discussed above, also fail to overcome this deficiency in Lambert et al. Therefore, claim 12 cannot be obvious over Lambert et al. in view of Wong et al. Withdrawal of the rejection of claim 12 is respectfully requested. Claims 13-15, 17, 18, and 24, which depend from claim 12, are likewise patentable over the combination of Lambert et al. and Wong et al. Withdrawal of the rejection of these claims is also respectfully requested.

### **Conclusion**

The rejected claims have been shown to be allowable over the prior art. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Please apply any charges not covered or credits in connection with this filing to Deposit Account No. 50-3202 (ref. ARC2556N1).

Respectfully submitted,

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